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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,498	01/30/2002	Jong-Gu Park	57354-00002	5213

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EXAMINER	
MCGARRY, SEAN	
ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
11/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/066,498	PARK ET AL.	
	Examiner	Art Unit	
	/Sean R. McGarry/	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2007 and 02 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-19,24,25,31-35,37-40,46,47,50,51 and 62-67* is/are pending in the application.

4a) Of the above claim(s) *17-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-16, 24, 25, 31-35, 37-40, 46, 47, 50, 51and 62-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/22/07 has been entered.

It is noted that the previous Examiner indicated that he was willing to allow applicant to change their invention upon the filing of an RCE. The instant examiner will allow this change since it was agreed to before his receiving the application. Applicant should ensure that their response to this Official Action provides a claim set that complies with 37 CFR 1.121.

Applicant's election with traverse of the species "cancer", "leukemia" and "MYB" in the reply filed on 4/25/07 and 8/02/07 is acknowledged. The traversal is on the ground(s) that the search and examination would not be a burden and that there is a special feature linking the inventions species. This is not found persuasive because applicant provides no evidence or argument other than the statement that there is no burden and also the affirmation that the generic claims are indeed generic.

The requirement is still deemed proper and is therefore made FINAL.

Claims 17-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4/25/07.

Applicants arguments in regard to any previous rejection of record is moot in view of the invention change and the new grounds of rejection set forth below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12-16, 24, 25, 31-35, 37-40, 46, 47, 50, 51, and 62-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Conrad [US 6,054,299] in view of Moon et al [The Journal of Biological Chemistry Vol. 275, No. 7, pages 4647-4653, 2/18/2000].

The claimed invention is drawn to the invention as clearly set forth in the claims. The claims are clear and no interpretation of them for art application is needed.

Conrad teaches large circular single stranded nucleic acid molecules that comprise antisense regions. Figure 1 show pANTI which is about 3000 nucleotides in length. It is disclosed by Conrad et al to Use M13 bacteriophage in the construction of his single stranded vectors. It is disclosed to use the DNA single stranded intermediates, for example. At "1." In column 3 it is taught the use of his vectors for triplex and antisense applications. At column 1 it is taught the vectors of his invention can be used in vivo for "drug delivery". At column 4 it is disclosed that the vectors can contain more than one antisense sequence. At column 6 it has been taught the insertion of a 660 nucleotide antisense sequence inserted into the "gene block" portion of the pANTI vector. At column 9 it has been taught that there is no size limit for antisense inserts. Conrad has therefor taught a large single stranded nucleic acid molecule that is at least about 3000 nucleotides in length that comprises a bacteriophage or phagemid genome that comprises an antisense or triplex sequence that can be over 50

nucleotides in length, where there can be more than one antisense sequence. Conrad et al teach a stem loop type of antisense approach.

Conrad does not specifically teach the use of a lipid carrier nor does he teach an antisense sequence targeting a cancer gene such a MYB.

Moon et al have taught the use of "ribbon-type" antisense oligonucleotides to inhibit c-myb-1in leukemic cell lines. Moon et al disclose that the art has a need for improved antisense techniques and indicate that stem-loop structured antisense have shown success. Moon et al also teach the involvement of c-myb-1 in cancers such as leukemia and in cell proliferation and have taught that antisense targeting c-myb-1 have been partially successful in inhibiting tumor growth. Moon et al teach three antisense oligonucleotides that were used in making ribbon-type antisense to inhibit c-myb. It is taught that these antisense were used in cells in culture to test there stability. Furthermore it is disclosed to use liposomes (see page 4649, for example) which were routinely used in the antisense art at the time of invention.

One in the art would have been motivated to combine the teachings of the prior art to make the instantly claimed invention. Conrad has taught how to make single stranded nucleic acid molecules that have advantages for in vivo antisense applications such as for drug delivery. Moon et al have taught to make ribbon type antisense to stabilize the antisense from nucleases and have taught that stem-loop antisense have worked to inhibit c-myb in tumors. The nucleic acid molecules of Conrad are disclosed to be circular and utilize stem loops for antisense /triplex delivery to cells. One in the art would have appreciated that the use of a vector such as Conrads would be beneficial

for prolonged antisense applications since it is delivered in a vector form. one in the art would also have known to use art recognized delivery agents such as those used by Moon et al (cationic liposomes). One in the art upon making a c-myb Conrad type antisense vector would know to first test such vectors in cells in culture to ensure optimization of sequence, for example, since animal testing can be quite expensive.

The invention as a whole would therefore have been prima facie obvious to one in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Sean R. McGarry/ whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sean R McGarry/
Primary Examiner
Art Unit 1635